UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AMY VASQUEZ, Plaintiff, v. GLOUCESTER COUNTY, et al., Defendants.

HONORABLE JOSEPH E. IRENAS

CIVIL ACTION NO. 13-4146
(JEI/JS)

OPINION

APPEARANCES:

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Irenas, Senior District Judge:

Plaintiff Amy Vasquez brings this wrongful death pursuant to 42 U.S.C. § 1983 and associated state-law claims.[1] Pending before the Court is Defendant Defibtech, LLC's partial motion to dismiss Plaintiff's design defect and punitive damages claims. For the reasons set forth below, this motion will be granted.

[1] The Court exercises subject-matter jurisdiction pursuant to 28 U.S.C. § 1331 and § 1367.

I.

On July 7, 2011, attorney Peter N. Fiorentino ("Fiorentino") waited in a second floor conference room in the Gloucester County Courthouse in Woodbury, New Jersey. (Compl. ¶ 20) At an unspecified time, Fiorentino was scheduled to appear before a judge elsewhere on the second floor. (Id.) As he waited, Fiorentino suffered cardiac arrest. (Id.)

Following calls to 9-1-1, sheriff's officers responded to aid Fiorentino, but could not immediately locate an automated external defibrillator ("AED"). (Id. ¶¶ 21-22) AEDs were ultimately found on the first and third floors of the building, but unspecified reports indicated that an AED malfunctioned at the scene. (Id. ¶¶ 22-23) At least one of the two AEDs in the courthouse were designed and manufactured by Defendant Defibtech, LLC, serial number: 101018832. (Id. ¶ 56)

At some point after the officers responded, Gloucester County Emergency Medical Services also responded to the scene, and Fiorentino regained a pulse before he was transported to Underwood Hospital. (Id. ¶¶ 23-24) However, Fiorentino never regained consciousness and died later that day. (Id. ¶ 26)

The Medical Examiner determined that anoxic encephalopathy caused Fiorentino's death. (Id. ¶ 27) Specifically, Fiorentino suffered an anoxic brain injury because of a lack of oxygen flowing to his brain for several minutes on July 7th. (Id.)

On July 8, 2013, Plaintiff Amy Vasquez ("Vasquez"), Fiorentino's widow and executor of his estate, brought this suit to recover for his death. (Compl. ¶¶ 1-3) Among other allegations, Vasquez asserts the following claims against Defibtech: defective design, failure to warn, wrongful death, a survival action, loss of consortium, and punitive damages. On December 13, Defibtech moved under Rule 12(b)(6) to dismiss Vasquez's design defect claim and her demand for punitive damages under the New Jersey Products Liability Act. Vasquez timely opposed this motion on January 7, 2014, and the motion is now ripe for consideration.

II.

Federal Rule of Civil Procedure 12(b)(6) provides that a court may dismiss a complaint "for failure to state a claim upon which relief can be granted." To survive a motion to dismiss, a complaint must allege facts that raise a right to relief above the speculative level. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see also* Fed. R. Civ. P. 8(a)(2).

When considering a Rule 12(b)(6) motion, the reviewing court must accept as true all allegations in the complaint and view them in the light most favorable to the plaintiff. *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008). In reviewing the allegations, a court is not required to

accept sweeping legal conclusions cast in the form of factual allegations, unwarranted inferences, or unsupported conclusions. *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997). Instead, the complaint must state sufficient facts to show that the legal allegations are not simply possible, but plausible. *Phillips*, 515 F.3d at 234. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

III.

Defibtech's motion seeks to dismiss Vasquez's claims for design defect and punitive damages. Each is addressed in turn.

A.

The New Jersey Products Liability Act governs the potential liability of health care providers for the manufacture and sale of medical devices. N.J.S.A. 2A:58C-11. As a result, Vasquez's product liability claim for the defective design of Defibtech's AED is governed by N.J.S.A. 2A:58C-2, which provides that:

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its

> intended purpose because it: . . . (c) was designed in a defective manner.

When considering a defective design product liability claim, New Jersey law requires a plaintiff to show that a "product was defective, that the defect existed when the product left the defendant's control, and that the defect caused injury to a reasonably foreseeable user." *Donlon v. Gluck Group, LLC*, No. 09-cv-5379 (JEI/KMW), 2011 WL 6020574, at *3 (D.N.J. Dec. 2, 2011) (quoting *Feldman v. Lederle Labs.*, 97 N.J. 429, 449 (1984)). This requires a plaintiff to prove:

> either that the product's risk outweighed its utility or that the product could have been designed in an alternative manner so as to minimize or eliminate the risk of harm. Plaintiffs who assert that the product could have been designed more safely must prove under a risk-utility analysis the existence of an alternative design that is both practical and feasible.

Schraeder v. Demilec (USA) LLC, No. 12-cv-6074 (FSH), 2013 WL 5770670, at *2 (D.N.J. Oct. 22, 2013) (quoting *Lewis v. Am. Cyanamid Co.*, 155 N.J. 544, 570-71 (1998)). In other words, a plaintiff may pursue a design defect claim by contending that its risk outweighs its harm, or that an alternate design exists, in accordance with a risk-utility analysis. *Schraeder*, 2013 WL 5770670, at *2. Though there is no "per se rule that Plaintiffs must, under all circumstances, provide a reasonable alternative design," a plaintiff must plead either that the product's risk

outweighs its harm, or that an alternate design exists, in order to state a claim for a design defect under the Product Liability Act. *Id.*

In light of this standard, the Court must dismiss Vasquez's design defect claim for failure to state a claim. Vasquez's Complaint omits any mention of any alternative design for the AEDs at issue and also omits any allegation regarding the risks inherent in the design of Defibtech's AEDs. At its core, Vasquez's Complaint simply alleges that Defibtech manufactured at least one of the two AEDs in the Gloucester County Courthouse, and that "Hospital staff reported that an AED used to treat [Fiorentino] malfunctioned by canceling a charge in preparation for a shock," leading to Fiorentino's death. (Compl. ¶¶ 56-57) These conclusory allegations fail to address a reasonable alternative design or the risk of harm inherent in the design of Defibtech's AED. As a result, the Court will dismiss Vasquez's design defect claim against Defibtech.

B.

Defibtech also seeks dismissal of Vasquez's demand for punitive damages, pled as a standalone claim in Count Three and additionally demanded within her product liability claim for failure to warn asserted in Count Seven. Vasquez's opposition does not address Defibtech's argument.

The Product Liability Act generally prohibits the award of punitive damages. In relevant part:

> Punitive damages shall not be awarded if a drug or device . . . which caused the claimant's harm was subject to premarket approval or licensure by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq. and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the Food and Drug Administration and applicable regulations, including packaging and labeling regulations.

N.J.S.A. 2A:58C-5(c). The statute contains one exception that permits a plaintiff to seek punitive damages "where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the [FDA's] regulations."[2] *Id.*

An AED, defined as a "device" under the Federal Food, Drug, and Cosmetic Act at 21 U.S.C. § 321(h), is classified as a Class III device by the FDA. 21 C.F.R. § 870.5310. This classification subjects AEDs to the FDA's premarket approval process pursuant to 21 U.S.C. § 360e(a), and as a result, the

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[2] Defibtech contends that that this provision is preempted by federal law, and therefore Vasquez cannot state a claim for punitive damages as a matter of law. *See McDarby v. Merck & Co., Inc.*, 401 N.J. Super. 10, 87-94 (App. Div. 2008). However, other courts have reviewed the grounds for federal preemption of the Product Liability Act's punitive damages provision and reached the opposite conclusion. *See, e.g., Forman v. Novartis Pharms. Corp.*, 793 F.Supp.2d 598, 601-10 (E.D.N.Y. 2011). The Court need not address whether preemption applies because, as described *infra*, Vasquez's allegations are insufficient to state a claim for punitive damages under this provision.

Product Liability Act generally prohibits an award of punitive damages. Furthermore, Vasquez's Complaint simply alleges that the AED was used for its intended purpose, but that the warnings were insufficient in spite of Defibtech's continuing obligations to warn users of the dangers associated with the AED. (Compl. ¶¶ 60-65) These allegations lack any contention or inference that Defibtech withheld or misrepresented information to the FDA regarding the AED's safety, the threshold for permitting punitive damages. The Court must therefore dismiss the claim for punitive damages within the failure to warn products liability claim asserted in Count Seven, and also dismiss the standalone claim for punitive damages asserted in Count Three.[3]

IV.

Based on the foregoing, the Defendants' partial motion to dismiss the Plaintiff's design defect and punitive damages claim will be granted. An appropriate Order accompanies this Opinion.

Date: 4/21/14

Joseph E. Irenas, S.U.S.D.J.

[3] Though not discussed in the exceedingly short briefs, Vasquez also demands punitive damages in three common-law claims for wrongful death (Count Eight), a survival action (Count Nine), and loss of consortium (Count Ten). Because Defibtech's motion only concerns Vasquez's demand for punitive damages on the product liability claim, the Court does not address Vasquez's three common-law claims and the associated punitive damages demands.